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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,538	06/26/2003	Anders Magnusson	12389-004001 / PD53566US0	5773
26191 7590 03/27/2008 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/606,538	Applicant(s) MAGNUSSON, ANDERS	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7-10,66-68 and 72-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7-10,66-68 and 72-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/21/07</u> . | 6) <input type="checkbox"/> Other: _____ |

ETAILED ACTION

Response to Amendment

1. Applicant has amended independent claims 1 and 66 to recite a tubular body that includes a loop formed by pulling the claimed elongate member. A tubular body including a loop had been listed in the restriction requirement mailed November 8, 2005 as species 4 of group I, which was not elected by applicant. However upon further review of that requirement, examiner notes that because claim 1 is a generic claim and because the tubular body of species (1) (which was elected by applicant) can physically include a loop while still conforming to the limitations of the species, the amendment does not prompt an election by original presentation and all currently pending claims will be examined herein.

Response to Arguments

2. Applicant's arguments with respect to claims 1-3, 7-10, 66-68 and 72-75 have been considered but are moot in view of the new ground(s) of rejection. Briefly, in response to applicant's argument that Brennen teaches a catheter that must be manually steered and is not steered by virtue of abutment of the instant stop member with an introducer hub or other obstacle, it is noted that this obstacle is not recited in amended claim 1. If one were to give independent claims 1 and 66 their broadest reasonable interpretation, these claims recite that the insertion of the catheter alone (without any force applied to the stop member and attached wire or without the aid of any obstacle or other physical entity) results in the formation of the loop at the distal end of the catheter. This is not how the claimed device operates; the obstacle is a necessary feature for one of ordinary skill in the art to use the claimed device. Thus claim 1 is not enabled by the disclosure as originally filed. In light of this, at least the combined teaching

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of Brennen and Hata still renders claims 1- 3, 8-10, 66-68, 73-75 and newly presented claims 76-81 unpatentable.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 7-10 and 76-78 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure as originally filed does not provide support for a tubular member whose insertion in any other arbitrary physical entity accomplishes the loop formation as claimed. Claim 1 omits the recitation of the introducer apparatus or other entity which is required for the insertion of the tubular catheter body to result in loop formation because the stop member must abut that other entity to cause pulling of the wire to form the loop. The following is cited from applicant's disclosure as support for examiner's position: "The stop abuts the proximal end of the introducer when the catheter is sufficiently positioned within the introducer, thereby causing the elongate member to become stretched." (Specification, page 5, lines 13-15) It is clear from this passage that without the presence of the introducer and the physical movement and interaction of the catheter with the introducer, the stop member will not be stretched to form the claimed loop. Claims 2, 3, 7-10 and 76-78 are rejected as they depend from claim 1 and thus also contain new matter.

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5. Claims 66-68, 72-75 and 79-81 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure as originally filed does not provide support for a catheter comprising a first elongate member, protruding member and second elongate member, wherein the protruding, first elongate and second elongate members of the catheter are configured such that sliding of the first elongate member relative to the protruding member upon insertion of the catheter pulls the second elongate member to form a loop. It would appear from claim 66 as a whole that either the catheter is inserted into itself or that insertion of the catheter into any other arbitrary physical entity would cause the formation of the loop. As with claim 1, claim 66 lacks the recitation of the only entity which makes formation of the loop possible that is supported by the disclosure, e.g. an introducer apparatus. Claims 67, 68, 72-75 and 79-81 are rejected as they depend from claim 66 and thus also contain new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 3 recites the limitation "extends between the ring member and the pair of openings" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 7 recites the limitation "between the distal region of the catheter and the ring member" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 77 recites the limitation "to pull the distal portion of the tubular body into the loop" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 66-68 and 73-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennen et al (WO 93/04724)

With respect to **Claim 66**: Brennen teaches a steerable stylet assembly comprising a tubular body 10 (first elongate member) having a distal region 22, stop member 32 (protruding member) that extends outward from an outer surface of body 10, encircles at least a portion of the circumference of said body, and is slidably coupled to said tubular body, and elongate pull wire 12 (second elongate member) having a proximal end in proximal section 14 and a distal end in distal section 16. The distal end of pull wire 12 is fixedly attached (i.e. coupled) to said tubular body at its distal end 22. The proximal end of pull wire 12 is attached to the stop member 32 via its interconnection with lever 34 and clip 36, said lever 34 having a free end attached to slidable member 32. Brennen teaches that the first elongate member 10, stop member 32 and second elongate member 12 are configured such that inserting the first elongate member causes the stop member 32 to pull the second elongate member, forming a loop in the distal region of the first elongate member. The Office's position is based upon the fact that Brennen illustrates the displacement of the distal region of the tubular body in an x-y displacement graph in Fig. 14 depicting the plane of deformation or bending of the distal region 16, wherein the distal region of said first elongate member forms a loop. Further, the first elongate member is fully capable of

being inserted into any other physical entity where the entrance diameter is less than the diameter of the circle formed by the stop member 32, and the insertion of the first elongate member will cause the stop member 32 to abut the entryway of the other entity, which will in turn cause a pulling of the wire 12 that will deflect the distal end of the first elongate member to eventually form the loop illustrated in Fig. 14.

With respect to **Claim 67**: Tubular member 10 (first elongate member) taught by Brennen includes an inner lumen, an outer surface and first and second apertures 18 and 20 (pair of openings) passing between the outer surface and the inner lumen. Pull wire 12 (second elongate member) is attached at the distal end 22 of tubular body 10 and extends loosely outside said lumen for a predetermined distance, therefore also passing through said apertures. Thus the coupling of said second elongate member to the distal region of the first elongate member comprises the second elongate member passing through the pair of openings.

With respect to **Claim 68**: As can be seen in Fig. 1 of Brennen, the pull wire 12 (second elongate member) passes between said protruding member 32 and said pair of openings 18,20 along the outer surface of tubular body 10 (first elongate member).

With respect to **Claim 73**: Brennen teaches clip 36 (connector piece) attached to slidable member 32 which is itself attached to a proximal region of tubular body 10 (first elongate member).

With respect to **Claim 74**: The distal region of tubular body 10 (first elongate member) taught by Brennen is flattened between the openings 18,20 to provide a predetermined bias to curve away from wire 12 as the wire is drawn taut between said openings. This section of the distal region of

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body 10 between said openings has a first stiffness and the remainder of the body 10, i.e. the proximal region, has a second stiffness, wherein the first stiffness is less than the second stiffness.

With respect to **Claim 75**: The section of tubular body 10 (first elongate member) taught by Brennen and lying between said openings 18,20 defines a first stiffness from the distal end 22 to opening 18 immediately adjacent the proximal region having a second stiffness.

With respect to **claim 80**: The length of the second elongate member 12 taught by Brennen is adjustable to adjust the range of sliding of the protruding member 32 along the first elongate member 10 to pull the distal portion of the first elongate member into the loop inasmuch as the second elongate member 12 is a wire that can be cut or knotted behind the stop member by the user.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 79 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennen et al ('724).

With respect to **claim 79**: Brennen does not teach that the protruding member 32 interacts with an introducer upon insertion of the catheter to cause the first elongate member to slide relative to the protruding member to form the loop. However, since the device of Brennen is intended for use in a surgical site in a human body, introducers for gently inserting and placing catheters at the desired site are well known in the art. The catheter is inserted into the introducer, the resulting combined entity is guided to its desired site, and then the introducer is removed, leaving the catheter *in situ*. It would be obvious to one of ordinary skill in the art to modify the device of Brennen so as to include an introducer with a reasonable expectation of success to provide a means for gently inserting the catheter into the patient's body and placing the catheter at the desired site. The device fairly suggested by Brennen thus meets the limitation "wherein the protruding member interacts with an introducer upon insertion of the catheter to cause the first elongate member to slide relative to the protruding member to form the loop".

With respect to **claim 81**: Brennen does not teach that the loop formed in the distal region of the first elongate member 10 includes more than 180 degrees of curvature. However, catheters having anchoring elements in the form of complete loops or pigtails at an end region that include more than 180 degrees of curvature are well known in the art and provide a means for anchoring the catheter in the desired site to prevent movement during surgical operations, wherein fluid pressure from fluid flowing in the catheter can dislodge the catheter. Therefore, it

would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Brennen and Hata so as to form a loop in the distal region of the first elongate member 10 wherein the loop includes more than 180 degrees of curvature with a reasonable expectation of success to provide a catheter with a self-anchoring capability.

11. Claims 1-3, 8-10 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennen et al ('724) in view of Hata et al (U.S. Patent Application Publication No. 2001/0044625).

With respect to **Claim 1**: Brennen teaches a steerable stylet assembly comprising a tubular body 10 having a distal region 22, stop member 32 that encircles at least a portion of the circumference of tubular body 10 and is slidable along said tubular body, and at least one elongate member in the form of elongate pull wire 12 having a proximal end in proximal section 14 and a distal end in distal section 16 of tubular body 10. The distal end of pull wire 12 is fixedly attached (i.e. coupled) to said tubular body at said distal end 22. The proximal end of pull wire 12 is attached to the stop member 32 via its interconnection with lever 34 and clip 36, said lever 34 having a free end attached to stop member 32. Brennen teaches that the tubular catheter body 10, stop member 32 and elongate member 12 are configured such that inserting the tubular catheter body causes the stop member 32 to pull the elongate member forming a loop in the distal region of the catheter body. The Examiner's position is based upon the fact that Brennen illustrates the displacement of the distal region of the tubular body in an x-y displacement graph in Fig. 14 depicting the plane of deformation or bending of the distal region 16 to form a loop. Further, the catheter is fully capable of being inserted into any other physical entity where the entrance diameter is less than the diameter of the circle formed by the stop

member 32, and the insertion of the catheter will cause the stop member to abut the entryway of the other entity, which will in turn cause a pulling of the wire 12 that will deflect the distal end of the tubular body to eventually form the loop illustrated in Fig. 14.

Brennen does not teach that the proximal end of said elongate member is directly attached to said ring member. Hata teaches a steerable catheter with a steering mechanism. Such mechanism comprises a string or wire directly attached to a rotatable ring member for manual manipulation by a caregiver. Hata teaches that such a steering mechanism for catheters is well-known in the art ('625, ¶0022), therefore it would be obvious to one of ordinary skill in the art to modify the device of Brennen such that said elongate member is directly attached to said ring member 32 rather than attached thereto via a lever 34 and clip 36 with a reasonable expectation of success, as such attachment would still allow manipulation of the catheter's position by a caregiver.

With respect to **claim 2**: Tubular member 10 taught by Brennen includes an inner lumen, an outer surface and first and second apertures 18 and 20 (pair of openings) passing between the outer surface and the inner lumen. Pull wire 12 (elongate member) is attached at the distal end 22 of tubular body 10 and extends loosely outside said lumen for a predetermined distance, therefore also extending through said apertures. Thus the coupling of said second elongate member to the distal region of said tubular body comprises the second elongate member passing through the pair of openings.

With respect to **claim 3**: As can be seen in Fig. 1 taught by Brennen, the pull wire passes between said ring member 32 and said pair of openings 18,20.

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With respect to **claim 8**: Brennen teaches clip 36 (connector piece) attached to slidable member 32 which is itself attached to a proximal region of tubular body 10.

With respect to **Claim 9**: The distal region of tubular body 10 taught by Brennen is flattened between the openings 18,20 to provide a predetermined bias to curve away from wire 12 as the wire is drawn taut between said openings. This section of the distal region of body 10 between said openings has a first stiffness and the remainder of the body 10, i.e. the proximal region, has a second stiffness, wherein the first stiffness is less than the second stiffness.

With respect to **Claim 10**: The section of tubular body 10 taught by Brennen between said openings 18,20 defines a first stiffness from the distal end 22 to opening 18 immediately adjacent the proximal region having a second stiffness.

With respect to **claim 76**: The combined teaching of Brennen and Hata does not teach inserting the tubular catheter body into an introducer that causes interaction between the stop member and the introducer to pull the elongate member to form the loop in the distal region of the tubular catheter body. However, since the device of Brennen is intended for use in a surgical site in a human body, introducers for gently inserting and placing catheters at the desired site are well known in the art. The catheter is inserted into the introducer, the resulting combined entity is guided to its desired site, and then the introducer is removed, leaving the catheter *in situ*. It would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Brennen and Hata so as to include an introducer with a reasonable expectation of success to provide a means for inserting the catheter into the patient's body and placing the catheter at the desired site. The device fairly suggested by the combined teaching of Brennen and Hata thus

meets the limitation “wherein inserting the tubular catheter body into an introducer causes interaction between the stop member and the introducer to pull the elongate member to form the loop in the distal region of the tubular catheter body”.

With respect to **claim 77**: The length of the elongate member 12 taught by Brennen may be adjusted to adjust the degree of advancement required to pull the distal portion of the tubular body into the loop inasmuch as the elongate member 12 is a wire that can be cut or knotted behind the stop member by the user.

With respect to **claim 78**: The combined teaching of Brennen and Hata does not teach that the loop formed in the distal region of the tubular catheter body 10 includes more than 180 degrees of curvature. However catheters having anchoring elements in the form of complete loops or pigtails that include more than 180 degrees of curvature are well known in the art and provide a means for anchoring the catheter in the desired site to prevent movement during surgical operations, wherein fluid pressure from fluid flowing in the catheter can dislodge the catheter. Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Brennen and Hata so as to form a loop in the distal region of the tubular catheter body 10 wherein the loop includes more than 180 degrees of curvature with a reasonable expectation of success to provide a catheter with a self-anchoring capability.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennen et al (WO 93/04724) in view of Hata et al ('625) as applied to claim 1 above, and further in view of Maloney et al (U.S. Patent No. 4,906,230).

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With respect to **claim 7**: Brennen teaches a stainless steel pull wire and therefore does not teach a single length of thread. Hata also does not teach a single length of thread as an elongate member. Maloney teaches a steerable catheter employing a mechanism comprising a string-like element, e.g. chord, suture or cable or the like. ('230, Col. 2, lines 28-32) The wires taught by Brennen and Hata are considered herein to be a string-like element as taught by Maloney, and Maloney teaches that a suture (thread) is equivalent to a chord or cable (e.g. a wire). Therefore it would be obvious to one of ordinary skill in the art to modify the device of Brennen and Hata so as to substitute a thread as taught by Maloney with a reasonable expectation of success, as a thread will also provide the desired steering function.

13. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennen et al (WO 93/04724) in view of Maloney et al (U.S. Patent No. 4,906,230).

With respect to **Claim 72**: Brennen teaches a stainless steel pull wire and therefore does not teach a single length of thread. Maloney teaches a steerable catheter employing a mechanism comprising a string-like element, e.g. chord, suture or cable or the like. ('230, Col. 2, lines 28-32) The wires taught by Brennen and Hata are considered herein to be a string-like element as taught by Maloney, and Maloney teaches that a suture (thread) is equivalent to a chord or cable (e.g. a wire). Therefore it would be obvious to one of ordinary skill in the art to modify the device of Brennen so as to substitute a thread as taught by Maloney with a reasonable expectation of success, as a thread will also provide the desired steering function.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761